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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,305	02/18/2004	Yung-chi Cheng	Y03-100US	4833

7590 08/17/2006  
Henry D. Coleman  
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EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/781,305

**Applicant(s)**

CHENG ET AL.

**Examiner**

Traviss C. McIntosh

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 10,12,17-21,23-41 and 44-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9,11,13-16,22,42 and 43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 1/21/05 & 5/26/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 10, 12, 17-21, 23-41, and 44-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/5/2006. Applicants argued that the MPEP states that restriction is only proper if a serious burden is placed on the examiner, and that they believe examination of the originally filed claims would not place a serious burden on the examiner. Applicants then state that all of the originally restricted claims are directed to patentably distinct chemical compounds which would not impose a heavy burden of the examination on the examiner. Applicants then state that they believe the originally filed claims are sufficiently narrow to allow the examiner to determine patentability without being subject to a serious burden. The examiner respectfully disagrees. Applicants compounds claimed cover thousands and thousands of possible compounds, some with sugars, some without, some with purine bases, some with pyrimidine bases, some being deoxy-sugars, some dideoxy-sugars, some are not deoxy-sugars. A search of the originally claimed compounds could not be made by searching a single drawn structure, but would require multiple searches of divergent compounds. Applicant's even state "all of the originally restricted claims are directed to patentably distinct chemical compounds/composition..." (see sentence bridging pages 2-3 of response), thus applicants believe them to also be distinct. It is noted, the examiner is unclear if applicants intended this to mean the claimed compounds are patentably distinct from each other, or the group as a whole contains patentably distinct compounds in relation to the rest of the compounds in the world. It is noted that applicants failed to provide any

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guidance or reasons as to why they believed the examiner's restriction requirement is wrong, but only that they believe the original claims were sufficiently narrow and would not cause a serious burden. These statements are closer to opinions than fact based arguments, and as such, are not sufficient.

Moreover, it is noted that the elected species does not fall within the elected group, nor fall within the scope of the claimed genus. Claim 1 of the instant application has a proviso which delimits the elected species from the group. However, it is noted that the examiner has withdrawn the species requirement and will examine the elected group VII as it relates to compounds and compositions comprising compounds of formula IV having a pyrimidine base wherein Z is O.

An action on the merits of claims 1-9, 11, 13-16, 22, and 42-43 is contained herein below.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 42 and 43 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Objections***

Claims 1, 2, 6, 7, 22, and 42-43 are objected to for containing withdrawn or non-elected subject matter. Applicants should delete all subject matter in the claims drawn to non-elected inventions.

Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 9 provides that the compound of claim 1 has the variable O in the Z position of the compound, however, this is all Z can be pursuant to the restriction requirement and election, as such, claim 9 is not seen to limit claim 8, 6, 2, or 1, those from which it depends.

Claim 11 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 11 provides that R<sup>2</sup> (of claim 6 ultimately) is H. However, claim 6 provides that R<sup>2</sup> is one of the 2 claimed “Nu” containing moieties, thus cannot be H. Applicants cannot limit R<sup>2</sup> to something which it has been delimited from being in a previous claim from which it depends.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 11, 13-16, 22, and 42-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation that X is optionally C<sub>1</sub>-C<sub>4</sub> alkyl, and the claim also recites X is preferably CH<sub>3</sub>, which is the narrower statement of the range/limitation. Applicants also state that R<sup>3</sup> is optionally C<sub>1</sub>-C<sub>4</sub> alkyl, and the claim also recites R<sup>3</sup> is preferably CH<sub>3</sub>. All instances of further defining a preferable variable are indefinite for the same reasons (for example in claim 1's definitions of R<sup>4</sup>, R<sup>5</sup>, R<sub>a</sub>, Y, and n).

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Claims 42 and 43 provide for the use of compounds of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 22 is indefinite wherein the claim is drawn to a composition comprising an "effective amount" of the compound of claim 1. The term, "effective amount" is indefinite where the claim fails to state the function which is to be rendered effective. See *In re Frederiksen*, 102 USPQ 35 (CCPA 1954).

All claims which depend from an indefinite claim are also indefinite. *Ex parte Cordova*, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).

The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

Claim 11 is rejected under 35 U.S.C 112, fourth paragraph, for not further limiting the subject matter claimed.

Claim 11 provides that the compound of claim 9 has H for R<sup>2</sup>. Claim 9 depends from claim 8, which depends from claim 6, which provides that R<sup>2</sup> is either the Nu-[-P-O-]-P~ group or the Nu-C(O)~ group. Thus claim 6 does not allow R<sup>2</sup> to be H, and cannot be subsequently limited to H.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Hrebebecky et al. (“Synthesis of 1-(2,3-dideoxy-4-C-methyl- $\beta$ -D-glycero-Pent-2-enofuranosyl)thymine, 1-(2,3-dideoxy-4-C-methyl- $\beta$ -D-glycero-pentofuranosyl)thymine, and 1(4-C-Azidomethyl-2-deoxy- $\beta$ -D-threo-pentofuranosyl)thymine”, Collect. Czech. Chem. Commun., vol 58, pp 1668-1674, 1993).

Claims 1 and 2 of the instant application are drawn to various 4'-substituted pyrimidine nucleosides and compositions comprising the same.

Hrebebecky et al. disclose a compound which anticipates claims 1 and 2 of the instant application, and compositions comprising the same. Hrebebecky et al. disclose compound IX on page 1669 which has a pyrimidine base, methyl in the instant application's R position; H in the instant applications R<sup>2</sup>, R<sup>3a</sup>, and R<sup>3b</sup> positions; and methyl in the R<sup>3</sup> position. Hrebebecky et al. also teach of compositions comprising the same (see top paragraph of page 1673).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Haraguchi et al. (Allylic Substitution o 3',4'-Unsaturated Nucleosides: Organosilicon-based Stereoselective



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Access to 4'-C-Branched 2'3'-Didehydro-2',3'-dideoxyribonucleosides", J. Org. Chem., vol 61, pp 821-858, 1996).

Haraguchi et al. disclose compound number 26, on page 854, which anticipates claim 1 of the instant application. Compound 26 is seen to have a pyrimidine base where R is H; R<sup>1</sup> is an acyl group; R<sup>3a</sup> and R<sup>3b</sup> are H; R<sup>3</sup> is a propenyl group (n is 1 and Y is H of the instant application); and R<sup>2</sup> is an acyl group.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss C. McIntosh III  
Art Unit 1623  
August 11, 2006

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